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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,435	01/18/2002	Gideon Bollag	ONYX1028/1028div/Formal D	7344

7590

04/23/2003

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EXAMINER

SANDALS, WILLIAM O

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 04/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/054,435

Applicant(s)

Bollag et al.

Examiner

William Sandals

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 27, 2003
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 30, 31, and 36-67 is/are pending in the application.
- 4a) Of the above, claim(s) 36-67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 30, and 31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on Jan 18, 2002 is/are a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

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DETAILED ACTION

Election/Restriction

1. Applicant's election without traverse of Group I, claims 1-6, 30 and 31 in Paper No. 6, filed January 27, 2003 is acknowledged.
2. Claims 36-67 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected Groups II-X, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 6.

Priority

3. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The status of the parent US Application No. 09/079,812 has changed to an issued patent, and must be updated.

Drawings

4. New formal drawings are required in this application because recent changes to the MPEP, section 608.02(c) no longer allow deferral of submission of drawings pursuant to

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notification. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the Patent and Trademark Office no longer prepares new drawings. See the attached Draftsmans Review, PTO form 948.

Claim Objections

5. Claims 3, 30 and 31 are objected to because of the following informalities: Claim 3 recites at line 2, "which is of human". The phrase "which is of human" is not grammatically correct. The "of" may be replaced by "from a", or the claim may be amended by some other language which is suitable. Claim 30 depends from cancelled claim 26, and claim 31 depends from cancelled claim 27. Claims 30 and 31 must either be cancelled or amended to depend from one of claims 1-6, currently under consideration. Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

Claims 1 and 6 recite "a biologically-active fragment". The specification provides a definition of the meaning of the phrase "a biologically-active fragment" at page 7, lines 11-13.

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The definition states: “[b]y biologically active, it is meant that the polypeptide fragment possesses an activity in a living system or with components of a living system”. The “activity” which is referred to in this definition is not specified, and could be anything. Since the “activity” of the peptide may embrace anything, the definition is so uncertain that it does not convey a definition for “a biologically-active fragment” such that one of skill in the art would know the metes and bounds of the claimed “activity”. The examples provided in the specification at page 7, lines 13-18 do not define the “activity”, but merely state what it “could be”. Therefore, the claims are vague and indefinite. Amending claims 1 and 6 to recite the specific activities of a Rac-GEF polypeptide as described at page 7, lines 13-18 would cure this defect.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-3, 6, 30 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/23743 (Davies et al.).

Davies et al. teach a biologically active fragment of guanine nucleotide exchange factor (GEF) set forth in SEQ ID NO: 2. (see Davies et al. at pages 2-4 and sequence number 2, which is >95% identical to the corresponding amino acids of instant SEQ ID NO:2). The peptide has a

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guanine nucleotide exchange activity, as recited in claim 2. The human homologue has been partially characterized (see example 3) (relating to claim 3). The peptide is purified (see pages 9-12) (relating to claim 6). The peptide is produced from a nucleic acid, as recited in claim 30. The peptide is produced from a nucleic acid which hybridizes to bases 900-1482 of SEQ ID NO:1, as recited in claim 31 (corresponding to bases 694-1276 of sequence number 1).

10. Claims 1, 2, 6 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Chuang et al.

Chuang et al. teach the Rac-Gef peptide smgGDS at the abstract. smgGDS has guanine nucleotide exchange activity and binds to guanine-depleted Rac, as recited in claim 2. smgGDS is substantially purified, as recited in claim 6 (see the materials and methods section). smgGDS is produced from a nucleic acid sequence, as recited in claim 30.

A person shall be entitled to a patent unless -

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

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11. Claims 1-3, 6 and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by US 5,994,070 (Streuli et al.).

Streuli et al. teach at columns 4-6, an isolated Rac GEF protein, Trio, which is expressed from a nucleic acid, as recited in claims 1, 6, and 30. Trio has guanine nucleotide exchange activity and binds to Rac as recited in claim 2. Trio may be from a human, as recited in claim 3.

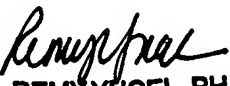
Conclusion

12. Certain papers related to this application are *welcomed* to be submitted to Art Unit 1636 by facsimile transmission. The FAX numbers are (703) 308-4242 and 305-3014. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by the applicant or applicant's representative, and the FAX receipt from your FAX machine is proof of delivery. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications should be directed to Dr. William Sandals whose telephone number is (703) 305-1982. The examiner normally can be reached Monday through Thursday from 8:30 AM to 7:00 PM, EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to the Tech Center customer service center at telephone number (703) 308-0198.

William Sandals, Ph.D.
Examiner
April 14, 2003


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